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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,860	08/29/2001	Richard E. Rothman	001107.00185	5063

22907 7590 08/24/2004

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/940,860	ROTHMAN ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *1 and 24-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/29/01 + 1/23/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group II (claims 2-23) in the reply filed on June 30, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. The information Disclosure statement filed on 8/29/2001, and 1/23//03 have been entered and considered.

3. Claims 2-23 are considered for examination in this office action. Claims 1, 24-32 are withdrawn from consideration in view of restriction/election. This is made FINAL.

4. This application is field on August 29, 2001, which claims the benefit of US provisional application 60/229,376 filed on August 31, 2000.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 recites PEU7 and PEU8. Amendment of the claim to recite sequence of these primers would obviate the rejection. The meets and bounds of the claim are unclear because it is not clear what these terms encompass or mean to describe.

B. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 recites "detecting an amplification

product of 416 *or* 811 base pairs, wherein a detected amplification product indicates the presence of template, which hybridizes to *both primers* in the *patient's blood.* The meets and bounds of the claim are unclear because it is not clear whether the primers hybridize to the patient's blood or to the DNA isolated from patient's blood. Further it is not clear that out of four primers, which both primers would hybridize to, said template and also it is not clear whether one amplification product is formed or two amplification products are formed using four PCR primers.

C. Claims 2-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites, "test sample which hybridize to *both primers* are amplified". The meets and bounds of the claims are unclear. The preceding step in claim 1 recites primers (plurality, which include two or more), and the recitation of both primers is unclear because it is not clear which two primers from plurality of primers would hybridize to produce an amplification product.

D. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 recites primer sequences in parentheses, which makes the claim indefinite and unclear because it is not clear that whether the limitations in the Parentheses followed by the terms PEU7 and PEU8, and PEU4 and PEU5 are required limitations, i.e. the SEQ ID NO. 1 and 2, and 3 and 4 or critical or not critical. Therefore, the metes and bounds of the claim are unclear.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2, 4-11, 14-15, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Corless et al. (J Clin Microbiol., Vol. 38, No. 5, pp 1747-1748, 2000).

Corless et al. teach a method of Claim 2, of performing polymerase chain reaction (PCR) comprising

(a) digesting reagents for PCR (PCR master mix) with a restriction endonuclease (see page 1747, col. 2, paragraph 4), wherein the reagents comprise, Taq DNA polymerase, reaction buffer, deoxynucleotide triphosphates and primers (see page 1748, col. 1, paragraph 6 under Materials and methods section)

(b) inactivating said restriction endonuclease but not said Taq DNA polymerase (see page1748, col. 2, paragraph 4-5);

(c and d) mixing test sample and the reagents to form a PCR mixture and subjected to PCR amplification to form an amplified product (see page 1748, col. 1, paragraphs 6-9, col. 2, paragraphs 4-5);

(e) detecting amplification product, which indicates the presence of target DNA in the test sample (see page 1749, col. 2, paragraphs 1-2 of Discussion section).

With regard to claims 4 and 8, Corless et al. teach the step of inactivating comprises heating to a temperature, which inactivates restriction endonuclease but not

Taq DNA polymerase at about 65 C for about 20 min (temperature below 85 C, for about 10 min) (see page 1748, col. 2, paragraphs 4-5);

With regard to claims 5-6, 11, Corless et al. teach that the test sample is a treated blood sample (blood treated to obtain a pure bacterial culture and treated to extract DNA from the culture) and the blood sample is from a patients suspected of systemic bacteremia (E.coli isolates from blood specimens) (see page 1748, col. 1, paragraph 3 of Materials and methods section);

With regard to claims 9-10, Corless et al. teach that the detection step employs agarose gel and the product is labeled with ethidium bromide and visualized under UV light (see page 1748, col. 2, paragraph 4, page 1749, col. 2, paragraph 2 of the Discussion section);

With regard to claims 7, 14-15, Corless et al. teach that the primers (PEU7 and PEU8 are arbitary terms which are noted as the equivalent to the primers taught by Corless et al.) hybridize to DNA sequences of highly conserved 16S RNA genes of eubacterial species (see page 1747, abstract);

With regard to claim 20, Corless et al. teach that the Taq DNA polymerase is not active under conditions used for the step of digestion (see page 1748, col. 2, paragraphs 4-5, wherein the digestion is carried out at 37 C, which is below the temperature (95 C) at which the Taq DNA polymerase is active).

Thus the disclosure of Corless et al. meets the limitations in the instant claims.

B. Claim 2-4, 8-10, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by DeFilippes (Biotechniques, Vol. 10, No. 1, pages 26, 28, 30, 1991).

The following rejections are based on the broad reasonable interpretation of the instant claims. As noted in MPEP 2111.03 - The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). The instant claims are in comprising format and does not exclude addition of any additional step or element.

DeFilippes teaches a method of Claim 2, of performing polymerase chain reaction (PCR) comprising

(a) digesting reagents for PCR with a restriction endonuclease wherein the reagents comprise, reaction buffer, deoxynucleotide triphosphates and primers, template DNA which is a part of a DNA polymerase (see page 26, col. 3, line 34, page 28, col. 1, lines 1-3, paragraph 1 of Materials and methods section, Fig. 1-2)

(b) inactivating said restriction endonuclease but not said Taq DNA polymerase (see page 28, col. 1, paragraph 1 of Materials and methods section);

(c and d) mixing test sample and the reagents to form a PCR mixture and subjected to PCR amplification to form an amplified product (see page 28, col. 1, paragraph 1 of Materials and methods section);

(e) detecting amplification product, which indicates the presence of target DNA in the test sample (see page 28, Fig. 1-2).

With regard to claim 3, DeFilippes teaches that the restriction endonuclease is Alu I (see page 28, Fig. 1-2);

With regard to claims 4 and 8, DeFilippes teaches the step of inactivating comprises heating to a temperature which inactivates restriction endonuclease but not Taq DNA polymerase at about 65 C for about 20 min (temperature at 90 C, for 20 min, about includes, 70, 80, or 90 C) (see page 28, col. 1, paragraph 1 of Materials and methods section);

With regard to claims 9-10, DeFilippes teaches that the detection step employs agarose gel and the product is labeled with ethidium bromide and visualized under UV light (see page 28, Fig. 1-2);

With regard to claim 18, DeFilippes teaches that the method comprises amplifying amplification product using primers that hybridize to single 16S RNA species (within the template) (see page 28, col. 3, paragraph 1, Fig. 2).

Thus the disclosure of DeFilippes meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 13, 17,19, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corless et al. (J Clin Microbiol., Vol. 38, No. 5, pp 1747-1748, 2000) in view of Lu et al. (J Clin Microbiol., Vol. 38, pp. 2076-2080, 2000).

Corless et al. teach a method of performing polymerase chain reaction (PCR) comprising

(a) digesting reagents for PCR (PCR master mix) with a restriction endonuclease (see page 1747, col. 2, paragraph 4), wherein the reagents comprise, Taq DNA polymerase, reaction buffer, deoxynucleotide triphosphates and primers (see page 1748, col. 1, paragraph 6 under Materials and methods section)

(b) inactivating said restriction endonuclease but not said Taq DNA polymerase (see page1748, col. 2, paragraph 4-5);

(c and d) mixing test sample and the reagents to form a PCR mixture and subjected to PCR amplification to form an amplified product (see page 1748, col. 1, paragraphs 6-9, col. 2, paragraphs 4-5);

(e) detecting amplification product, which indicates the presence of target DNA in the test sample (see page 1749, col. 2, paragraphs 1-2 of Discussion section).

However, Corless et al. did not teach the performing PCR using body fluids such as cerebral fluids, and performing restriction digestion on amplified PCR products.

Lu et al. teach a PCR method for detecting common bacterial pathogens in cerebral fluid, urine, wherein the method comprises PCR amplification a pair of primers and restriction digestion of amplified products (with regard to the instant claim 17) with one or more restriction enzymes (with regard to the instant claims 21-22) (see page 2076, col. 2, paragraph 3, page 2077, col. 1, paragraph 1, page 2078, Fig. 2).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method of performing PCR as taught by Corless et al. with a step of including restriction digestion with restriction endonucleases as taught by Lu et al. to achieve expected advantage of developing an improved and sensitive PCR method because Lu et al. taught that use of one set of primers designed based on conserved sequence of the 16S rRNA genes of various bacteria in a PCR amplification and PCR products from different bacteria would have different restriction patterns and PCR products from different isolates of the same bacteria would have same restriction pattern, which would allow identification of bacteria in a sample (See page 2079, col. 1, paragraph 1 of Discussion section). An ordinary practitioner would have been motivated to modify the method of performing PCR with

the incorporation of an additional step that is, restriction digestion of amplified PCR product as taught by Lu et al. to enhance sensitivity and efficiency of the PCR based detection of bacteria by differentiating the restriction patterns.

B. Claims 12-13, 17,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corless et al. (J Clin Microbiol., Vol. 38, No. 5, pp 1747-1748, 2000) in view of Mariani et al. (USPN. 5,654,141).

Corless et al. teach a method of performing polymerase chain reaction (PCR) comprising

(a) digesting reagents for PCR (PCR master mix) with a restriction endonuclease (see page 1747, col. 2, paragraph 4), wherein the reagents comprise, Taq DNA polymerase, reaction buffer, deoxynucleotide triphosphates and primers (see page 1748, col. 1, paragraph 6 under Materials and methods section)

(b) inactivating said restriction endonuclease but not said Taq DNA polymerase (see page1748, col. 2, paragraph 4-5);

(c and d) mixing test sample and the reagents to form a PCR mixture and subjected to PCR amplification to form an amplified product (see page 1748, col. 1, paragraphs 6-9, col. 2, paragraphs 4-5);

(e) detecting amplification product, which indicates the presence of target DNA in the test sample (see page 1749, col. 2, paragraphs 1-2 of Discussion section).

However, Corless et al. did not teach the performing PCR using body fluids such as cerebral fluids, urine and performing PCR with a pair of primers specific 16S RNA and restriction digestion on amplified PCR products.

Mariani et al. teach a PCR method of claims 12-13, 17, 19, for detecting common bacterial pathogens in cerebral fluid, urine, wherein the method comprises PCR amplification a pair of primers (see col. 4, line 31-67, col. 5, line 1-12) and restriction digestion of amplified products using restriction endonucleases (see col. 8, line 20-32).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method of performing PCR as taught by Corless et al. with a step of including restriction digestion with restriction endonucleases as taught Mariani et al. to achieve expected advantage of developing an improved and sensitive PCR method because Mariani et al. taught that amplification using one set of primers designed based on conserved sequence of the 16S rRNA genes of various bacteria followed by restriction digestion of the PCR products would allow in the detection of species-specific sequence polymorphism and aid in recognizing sequence differences (see col. 8, lines 20-32). An ordinary practitioner would have been motivated to modify the method of performing PCR with the incorporation of an additional step that is, restriction digestion of amplified PCR product as taught by Mariani et al. to enhance sensitivity and efficiency of the PCR based species-specific detection of bacteria by differentiating the restriction patterns.

C. Claims 16, is rejected under 35 U.S.C. 103(a) as being unpatentable over Corless et al. (J Clin Microbiol., Vol. 38, No. 5, pp 1747-1748, 2000) in view of Dodge et al. (USPN. 6,054,278).

Corless et al. teach a method of performing polymerase chain reaction (PCR) comprising

(a) digesting reagents for PCR (PCR master mix) with a restriction endonuclease (see page 1747, col. 2, paragraph 4), wherein the reagents comprise, Taq DNA polymerase, reaction buffer, deoxynucleotide triphosphates and primers (see page 1748, col. 1, paragraph 6 under Materials and methods section)

(b) inactivating said restriction endonuclease but not said Taq DNA polymerase (see page1748, col. 2, paragraph 4-5);

(c and d) mixing test sample and the reagents to form a PCR mixture and subjected to PCR amplification to form an amplified product (see page 1748, col. 1, paragraphs 6-9, col. 2, paragraphs 4-5);

(e) detecting amplification product, which indicates the presence of target DNA in the test sample (see page 1749, col. 2, paragraphs 1-2 of Discussion section).

However, Corless et al. did not teach sequencing the amplified product to detect the template DNA

Dodge et al. teach a PCR method for detecting microorganisms based on RNA gene polymorphism, wherein the method comprises PCR amplification of 16S rRNA gene regions followed by sequencing the amplified products to detect the sequence variation and identification of microorganisms (see col. 4, line 27-50col. 17, line 40-44, col. 18, line 1-39).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method of performing PCR as taught by Corless et al. with a step of including sequencing the amplified product as taught by Dodge et al. to achieve expected advantage of developing an improved and sensitive PCR method because Dodge et al. taught that detection of unknown bacteria

based on the sequence variation in relation to the sequences from known / reference microorganisms would provide information in determining the species, subspecies or strain of the microorganism (see col. 2, line 7-19). An ordinary practitioner would have been motivated to modify the method of performing PCR with the incorporation of an additional steps of sequencing the amplified PCR product as taught by Dodge et al. to enhance the sensitivity and efficiency of the PCR based detection of bacteria by differentiating the bacterial species or strain variation based on the sequence similarities and dissimilarities.

D. Claims 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corless et al. (J Clin Microbiol., Vol. 38, No. 5, pp 1747-1748, 2000) in view of Dodge et al. (6,054,278), Everett et al. ((USPN. 6,261,769) and Dunbar et al. (Appl. Environ. Microbiol., Vol. 65(4), pp. 1662-1669, 1999).

Corless et al. teach a method of performing polymerase chain reaction (PCR) comprising

(a) digesting reagents for PCR (PCR master mix) with a restriction endonuclease (see page 1747, col. 2, paragraph 4), wherein the reagents comprise, Taq DNA polymerase, reaction buffer, deoxynucleotide triphosphates and primers (see page 1748, col. 1, paragraph 6 under Materials and methods section)

(b) inactivating said restriction endonuclease but not said Taq DNA polymerase (see page1748, col. 2, paragraph 4-5);

(c and d) mixing test sample and the reagents to form a PCR mixture and subjected to PCR amplification to form an amplified product (see page 1748, col. 1, paragraphs 6-9, col. 2, paragraphs 4-5);

(e) detecting amplification product, which indicates the presence of target DNA in the test sample (see page 1749, col. 2, paragraphs 1-2 of Discussion section).

However, Corless et al. did not teach PCR primers selected from the group consisting of SEQ ID Nos. 1-4.

Dodge et al. teach a PCR method for detecting microorganisms based on RNA gene polymorphism, wherein the method comprises PCR amplification of 16S rRNA gene regions followed by sequencing the amplified products to detect the sequence variation and identification of microorganisms (see col. 4, line 27-50col. 17, line 40-44, col. 18, line 1-39). Dodge et al. also teach PCR primers designed based on 16S rRNA regions that could be used in amplifying various regions of rRNA in microorganisms (see col. 6, lines 40-65) of which Seq ID No. 9 of the patent has 100% homology with the claimed SEQ ID NO. 1 (see attached sequence alignment).

Everett et al. teach a method for detecting bacteria based on amplification of 16S and 23S ribosomal genes, wherein the PCR primers were designed based on the conserved regions between 16S and 23S rRNA genes, of which SEQ ID . 6 and 26 which represent sequences of 16S rRNA gene comprise the instant claimed SEQ ID Nos. 2 and 3 (see attached sequence alignment).

Dunbar et al. teach sequences derived from 16 S rDNA gene, wherein the AF128731 clone of comprises SEQ ID No. 4 (see sequence alignment).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method of performing PCR as taught by Corless et al. with a step of including a step of primers designed based on known conserved regions of 16 S ribosomal gene of bacteria and identification of

bacteria based on sequence variation in conserved regions of 16S ribosomal gene as taught by Dodge et al. Everett et al. and Dunbar et al. An ordinary practitioner would have been motivated to modify the method of performing PCR with the incorporation of an additional steps of universal amplification of bacteria using PCR primers that hybridize to 16S rRNA/ rDNA conserved regions to enhance sensitivity and efficiency of the PCR based detection of various bacteria by differentiating the bacterial species or strain variation based on the sequences.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782 . The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
August 19, 2004

JEHANNE SITTON
PRIMARY EXAMINER
8/19/04